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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/771,552

02/03/2004

Leonard Bell

ALXN-PO1-114

6183

28120

7590

03/21/2008

ROPES & GRAY LLP

PATENT DOCKETING 39/41

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BOSTON, MA 02110-2624

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT

PAPER NUMBER

1644

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/771,552	<b>Applicant(s)</b> BELL ET AL.	
	<b>Examiner</b> F. Pierre VanderVegt	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 109-120 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 109-120 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20080110</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The instant application, filed on February 3, 2004, does not claim priority to any earlier application.

Claims 1-108 and 121-171 have been canceled.

Claims 109-120 are currently pending and are the subject of examination in the present Office Action.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 10, 2008 has been entered.

In view of Applicant's amendment filed January 10, 2008 no outstanding ground of rejection is maintained.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 109-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexion press release dated January 6, 2003 (CG on form PTO-1449 filed 5/10/2007, of record) in view of Collard et al (Arterioscler Thromb Vasc Biol. [1999]19(11):2623-2629; U on form PTO-892, newly cited).

The Alexion press release teaches the use of the anti-C5 antibody compound eculizumab (h5G1.1-scFv) for the treatment of subjects with the hemolytic disease paroxysmal nocturnal hemoglobinuria (see entire document). It is noted that h5G1.1-scFv is the same compound recited in claim 111. The Alexion press release is silent about the treatment of NO deficiency in paroxysmal

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nocturnal hemoglobinuria. However, because the compound used to treat paroxysmal nocturnal hemoglobinuria in the Alexion press release and the instantly claimed compound to treat NO deficiency in paroxysmal nocturnal hemoglobinuria are the same, the treatment of NO deficiency in paroxysmal nocturnal hemoglobinuria would be an inherent property of the anti-C5 antibody compound eculizumab (h5G1.1-scFv). The prior art teaching anticipates the claimed invention.

The Alexion press release does not specifically link the hemolytic disease with NO deficiency or the effect of h5G1.1-scFv on NO levels.

Collard teaches the treatment of hypoxic HUVECs with h5G1.1-scFv (see entire document). Collard teaches that terminal complement component C5b-9 deposition results in a functional loss of NO-dependent relaxation (page 2625 in particular), increases VCAM-1 expression and decreases cGMP levels (page 2623 and page 2625 in particular). Collard teaches that decreased cGMP levels may compromise vascular blood flow because of decreased endothelium-dependent relaxation and increased adhesion of neutrophils to the endothelium (page 2623 in particular). Collard teaches that h5G1.1-scFv treatment of the HUVECS attenuates C5b-9 deposition and preserves acetylcholine induced increases in cGMP after hypoxia/reoxygenation (page 2625 in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to use the h5G1.1-scFv antibody taught by the Alexion press release for the treatment of NO deficiency in a subject. One would have been motivated to treat NO deficiency with h5G1.1-scFv with a reasonable expectation of success by the showing of Alexion that h5G1.1-scFv treatment of PNH relieved hemolysis and the teachings of Collard that C5b-9 deposition during reoxygenation after a hypoxic event inhibited NO-mediated cGMP expression, which adversely affects vascular blood flow and attracts damaging neutrophils to the endothelial surface. Collard teaches that treatment with h5G1.1-scFv inhibits this C5b-9 deposition and attenuates cGMP loss.

Claims 112-114 are included because, while the references are silent about the proportion of type III red blood cells, silence about a particular property does not necessarily constitute absence of that property. Also, claims 115-117 are included because, while the references are silent about the platelet counts in a subject, silence about a particular property does not necessarily constitute absence of that property. Furthermore claims 118-120 are included because, while the references are silent about the reticulocyte counts in a subject, silence about a particular property does not necessarily constitute absence of that property. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of

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ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

### ***Conclusion***

3. No claim is allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571)272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/  
Patent Examiner  
March 17, 2008

/David A Saunders/  
Primary Examiner, Art Unit 1644